



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4590]

Morton Grove Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 21 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* of December 2, 2019. The document announced the withdrawal of approval of 21 abbreviated new drug applications (ANDAs) from multiple applicants, effective January 2, 2020. The document erroneously included ANDA 076709 for Fentanyl Extended-Release Film, 25 micrograms (mcg)/hour (hr), 50 mcg/hr, 75 mcg/hr, 100 mcg/hr, held by Actavis Laboratories UT, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 577 Chipeta Way, Salt Lake City, UT 84108, and ANDA 077062 for Fentanyl Extended-Release Film, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, and 100 mcg/hr, held by Mayne Pharma LLC, 1240 Sugg Parkway, Greenville, NC 27834. This correction is being made because FDA previously withdrew the approval of ANDAs 076709 and 077062 in the *Federal Register* of November 18, 2019. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Monday, December 2, 2019, 84 FR 65986, appearing on page 65986 in FR Doc. 2019-25946, the following correction is made:

On page 65986, in the table, the entries for ANDAs 076709 and 077062 are removed.

Dated: July 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-14717 Filed: 7/9/2021 8:45 am; Publication Date: 7/12/2021]